

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Chapter 49A (16 Del.C., Ch. 49A)
16 DE Admin. Code 4470

EMERGENCY

ORDER

4470 State of Delaware Medical Marijuana Code

NATURE OF THE PROCEEDINGS:

This emergency regulation is being promulgated to ensure the availability of pediatric medical marijuana oils to qualifying patients under the age of 18, as dictated by Senate Bill 90 of the 148th Legislative Session. This includes revisions to existing regulations to allow for increased production of medical marijuana products to accommodate demand for pediatric medical marijuana oils. Revisions are also being made to allow for the application, qualification and registration of patients, and primary guardians, under the age of 18 with the Delaware Medical Marijuana Program. This emergency regulation adoption is necessary while the proposed rulemaking process is being completed to ensure the welfare of qualified patients under the age of 18 via the availability of medical marijuana. Delaware Health and Social Services ("Department") / Division of Public Health has determined that a compelling public interest exists to amend these regulations without prior notice or hearing.

NATURE OF PROPOSED AMENDMENT:

The proposed provides notice to the public that the Division of Public Health (DPH) intends to amend the existing 4470 State of Delaware Medical Marijuana Code to allow for registration of qualifying patients under the age of 18 with the Medical Marijuana Program and expand marijuana product production to meet the needs of these qualified patients.

SUMMARY OF THE PROPOSED AMENDMENT:

The existing 4470 State of Delaware Medical Marijuana Code does not adequately provide for the provision of medical marijuana products to qualifying patients as dictated by SB-90. The current regulations are being revised to allow for provision of these products, with restrictions, to qualifying patients under the age of 18, provide mechanisms to issue Registry Identification cards to these patients and ease restrictions on medical marijuana production to meet the increased demand expected. These revisions provide these patients and their guardians with the services and products provided to other patients under the existing 4470 State of Delaware Medical Marijuana Code.

FINDINGS OF FACT:

The Department finds that a compelling public interest exists which necessitates promulgation of an emergency regulation and requests emergency approval of these rule amendments to provide for the availability of medical marijuana products to qualified patients. The Department will receive, consider, and respond to petitions by any interested person for the reconsideration or revision thereof.

THEREFORE, IT IS ORDERED, to assure the welfare of qualifying patients under the age of 18 that the revised 4470 State of Delaware Medical Marijuana Code be adopted on an emergency basis without prior notice or hearing.

Rita M. Landgraf, Secretary, DHSS
July 15, 2015

4470 State of Delaware Medical Marijuana Code

Preamble

The Secretary of Delaware Health and Social Services adopts these Regulations in response to the authority vested in the Secretary by 16 Del.C. Ch. 49A, The Delaware Medical Marijuana Act. These Regulations establish the standards for the procedures for issuing a certificate of registration to qualified patients and primary caregivers. These Regulations provide a system of permitting and inspection, as well as governing confidentiality, payments of fees, and enforcement of these rules.

17 DE Reg. 738 (01/01/14)

Purpose

These Regulations shall be liberally construed and applied to promote their underlying purpose of protecting the

public's health.

1.0 State of Delaware Medical Marijuana Code

These Regulations shall hereby be known as the "State of Delaware Medical Marijuana Code."

2.0 Definitions

The following words and terms, when used in these Regulations, should have the following meaning, unless the context clearly indicates otherwise:

"Act" means the Delaware Marijuana Act, 16 **Del.C.** §§4901A *et seq.*

"Adulterated" means made impure or inferior by adding extraneous ingredients. Goods that are prepared in food establishments that are licensed facilities in response to 16 **Del.C.** §122(3)(u) and 16 **Del.C.** §134, and that contain marijuana for medical use by a registered patient, are not considered to be adulterated.

"Advisory board" means a nine member committee established, chaired, and appointed by the General Assembly of Delaware to evaluate and make recommendations to the state legislature and the Department.

"Applicant" means any person applying to participate in the Delaware Office of Medical Marijuana Program, hereinafter OMMP.

"Background check" means any person required to obtain a background check under this chapter shall submit fingerprints and other necessary information to the State Bureau of Identification in order to obtain a report of the person's entire criminal history record from the State Bureau of Identification or a statement that the State Bureau of Identification Central Repository contains no such information relating to that person. The report will include the person's entire federal criminal history record from the Federal Bureau of Investigation pursuant to Federal Bureau of Investigation appropriation of Title II of Public Law 92-544 (28 U.S.C. § 534) or a statement that the Federal Bureau of Investigation's records contain no such information relating to that person. A person required to obtain a background check under this chapter is responsible for any costs associated with obtaining the background check.

"Bona fide physician-patient relationship" means a treatment or counseling relationship between a physician and patient in which all the following are present:

- (1) The physician has reviewed the patient's relevant medical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant, in-person, medical evaluation of the patient.
- (2) The physician has created and maintained records of the patient's condition in accord with medically accepted standards.
- (3) The patient is under the physician's continued care for primary medical care or the debilitating condition that qualifies the patient for the Medical Marijuana Program.
- (4) The physician has a reasonable expectation that he or she will provide follow-up care to the patient to monitor the efficacy of the use of medical marijuana as a treatment of the patient's debilitating medical condition.
- (5) The relationship is not for the sole purpose of certifying for medical marijuana.

"Cardholder" means a registered patient or a registered designated caregiver who has been issued and possesses a valid registry identification card.

"Compassion center agent" means a principal officer, board member, employee, or agent of a registered compassion center who is 21 years of age or older and has not been convicted of an excluded felony offense, and has not been convicted of a drug misdemeanor within five years.

"Debilitating medical condition" means one or more of the following:

- (a) cancer, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), decompensated cirrhosis (hepatitis C), amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease), post-traumatic stress disorder (PTSD), intractable epilepsy, and agitation of Alzheimer's disease or the treatment of these conditions;
- (b) a chronic or debilitating disease medical condition or its treatment that produces one or more of the following: cachexia or wasting syndrome; severe, debilitating pain that has not responded to previously prescribed medication or surgical measures for more than three months or for which other treatment options produced serious side effects; intractable nausea; seizures; or severe and persistent muscle spasms, including but not limited to those characteristic of multiple sclerosis;
- (c) any other medical condition or its treatment added by the Department, as provided for in 16 **Del.C.** §4906A and Section 6.0 of this code.

"Department" means the Delaware Department of Health and Social Services.

"Designated caregiver" means a person who:

- (a) is at least 21 years of age unless the person is the parent or legal guardian of a minor who is a qualifying patient.
- (b) has agreed to assist with a patient's medical use of marijuana
- (c) has not been convicted of an excluded felony offense; and
- (d) assists no more than five qualifying patients with their medical use of marijuana.

"Excluded felony offense" means:

- (a) a violent crime defined in 11 **Del.C.** §4201(c), that was classified as a felony in the jurisdiction where the person was convicted; or
- (b) a violation of a state or federal controlled substance law that was classified as a felony in the jurisdiction where the person was convicted, not including:
 - (1) an offense for which the sentence, including any term of probation, incarceration, or supervised release, was completed 10 or more years earlier; or
 - (2) an offense that consisted of conduct for which 16 **Del.C.** Ch. 49A would likely have prevented a conviction, but the conduct either occurred prior to July 1, 2011, or was prosecuted by an authority other than the State of Delaware.

"Incidental amount of marijuana" means marijuana seeds, stalks and roots of the plant that are not included when calculating the allowable amounts of marijuana specified in these rules. This includes the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare a topical ointment, food or drink.

"Intractable epilepsy" means an epileptic seizure disorder for which standard medical treatment does not prevent or significantly ameliorate recurring, uncontrolled seizures or for which standard medical treatment results in harmful side effects.

"Marijuana" means the same as defined in 16 **Del.C.** §4701 (23).

"Marijuana paraphernalia" is limited to equipment, products and materials that are ordinarily used in planting, propagating, cultivating, growing, harvesting, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, ingesting, inhaling or otherwise introducing marijuana into the human body. It includes:

- (a) Scales and balances used or intended for use in weighing or measuring marijuana;
- (b) Separation gins and sifters, used or intended for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana;
- (c) Envelopes and other containers used or intended for use in packaging small quantities of marijuana for medical use;
- (d) Containers and other objects used or intended for use in storing medical marijuana; and
- (e) Objects used or intended for use in ingesting, inhaling or otherwise introducing marijuana into the human body, including but not limited to:
 - (1) Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens, permanent screens, hashish heads or punctured metal bowls;
 - (2) Water pipes;
 - (3) Carburetion tubes and devices;
 - (4) Smoking and carburetion masks;
 - (5) Roach clips, meaning objects used to hold burning marijuana cigarettes that have become too small or too short to be held in the hand;
 - (6) Chamber pipes;
 - (7) Carburetor pipes;
 - (8) Electric pipes;
 - (9) Air-driven pipes;
 - (10) Chillums;
 - (11) Bongs designed for marijuana and not for cocaine; or
 - (12) Ice pipes or chillers.

"Medical marijuana oil" means a resinous matrix of cannabinoids obtained from the Cannabis plant by solvent extraction, formed into oil.

"Medical marijuana waste" means unused, surplus, returned, or out of date medical marijuana, recalled medical marijuana, and any plant debris, including dead plants, all unused plant parts, and roots.

"Medical use" means the acquisition, possession, use, delivery, transfer or transportation of marijuana or paraphernalia relating to the administration of marijuana to treat or alleviate a registered patient's debilitating medical condition or symptoms associated with the registered patient's debilitating medical condition.

"Onsite assessment" means a visit by an employee of the Department for the purpose of ensuring compliance with the requirements of these rules.

"Pediatric Medical marijuana oil" means:

- a. "Cannabidiol oil" which is a processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than seven percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of cannabidiol per milliliter but not more than seven percent tetrahydrocannabinol; and
- b. "THC-A oil" which is a processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than seven percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of tetrahydrocannabinol acid per milliliter but not more than seven percent tetrahydrocannabinol; and
- c. any change in the oil formulation which is made by the Department based upon the recommendation of the advisory council Medical Marijuana Act Oversight Committee"

"Physician" means a properly licensed physician subject to 24 **Del.C.** Ch. 17. If the qualifying patient's debilitating medical condition is post-traumatic stress disorder, the physician must also be a licensed psychiatrist. If the qualifying patient is younger than 18 years of age, the physician must be a pediatric neurologist, pediatric gastroenterologist, pediatric oncologist or pediatric palliative care specialist.

"Post-Traumatic Stress Disorder" means that a patient meets the diagnostic criteria for Post-Traumatic Stress Disorder (PTSD), per DSM-5 or subsequent current edition, including symptoms of intense physical reactions such as tachycardia, shortness of breath, rapid breathing, muscle-tension, and sweating.

"Qualifying patient" means a person who has been diagnosed by a physician as having a debilitating medical condition.

"Registry identification card" means a document issued by the Department that identifies a person as a registered patient or registered designated caregiver.

"Responsible Party" means the parent or legal guardian with responsibility and decision-making capability for a qualifying patient or applicant. The Responsible Party will have primary responsibility for purchase, handling and dispensing of the medical marijuana products for the person under their charge.

"Tincture" means a mixture created from a concentrated extract of marijuana.

"Topical treatment" means a mixture or extract of marijuana made into a balm, lotion, ointment or rubbing alcohol solution, that is applied transcutaneously.

"Usable amount of medical marijuana for medical use" means six ounces or less of usable marijuana as defined below.

"Usable marijuana" means the dried leaves and flowers of the marijuana plant, and any mixture or preparation of those dried leaves and flowers, including but not limited to tinctures, ointments, and other preparations including medical marijuana oil, but does not include the seeds, stalks, and roots of the plant. It does not include the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare a topical administration, food, or drink.

"Verification system" means a phone or web-based system established and maintained by the Department that is available to law enforcement personnel and compassion center agents on a twenty-four-hour basis for verification of registry identification cards.

"Written certification" means a document dated and signed by a physician, stating that in the physician's opinion the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient's debilitating medical condition or symptoms associated with the debilitating medical condition. A written certification shall be made only in the course of a bona fide physician-patient relationship where the qualifying patient is under the physician's care for the qualifying patient's primary care or for the qualifying patient's debilitating condition after the physician has completed an assessment of the qualifying patient's medical history and current medical condition. The bona fide physician-patient relationship may not be limited to authorization for the patient to use medical marijuana or consultation for that purpose. The written certification shall specify the qualifying patient's debilitating medical condition.

17 DE Reg. 738 (01/01/14)

3.0 Qualifying Patient Identification Card Application Requirements

- 3.1 The Department shall issue a registry identification card to an applicant for the purpose of participating in the medical marijuana program upon the written certification of the applicant's physician, supporting application

documents and a non-refundable application fee with a personal check or a cashier's check made out to "Division of Public Health, Medical Marijuana Program." The following information shall be provided in the participant enrollment form submitted to the Department in order for a registry identification card to be obtained and processed.

- 3.2 An attached original written certification for patient eligibility form shall contain:
 - 3.2.1 the name, address and telephone number of the applicant's physician;
 - 3.2.2 the physician's clinical licensure;
 - 3.2.3 the patient applicant's name and date of birth;
 - 3.2.4 the medical justification for the physician's certification of the patient's debilitating medical condition;
 - 3.2.5 the physician's signature and date;
 - 3.2.6 the name, and address of the applicant as they appear on the applicant's government issued ID card, and date of birth of the applicant;
 - 3.2.7 the name, address and date of birth of the applicant's primary caregiver(s), if any;
 - 3.2.8 a reasonable xerographic copy of the applicant's Delaware driver's license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; State of Delaware issued identification card must be available for inspection/verification;
 - 3.2.9 the length of time the applicant has been under the care of the physician providing the medical provider certification for patient eligibility;
 - 3.2.10 the applicant's signature and date; and
 - 3.2.11 a signed consent for release of medical information related to the patient's debilitating medical condition, on a form provided by the medical marijuana program.
- 3.3 If the qualifying patient is under the charge of a Responsible Party as defined in these regulations:
 - 3.3.1 The Responsible Party must be identified on the initial application.
 - 3.3.2 If the qualifying patient is of an age where an ID to meet 3.2.6 and 3.2.8 above has not been issued, the Responsible Party's ID shall be used. If the qualifying patient has a government issued ID, information and IDs for both individuals shall meet 3.2.6 and 3.2.8 above.
 - 3.3.3 The physician must be a pediatric neurologist, pediatric gastroenterologist, pediatric oncologist or pediatric palliative care specialist and certify that:
 - 3.3.3.1 The qualifying patient has intractable epilepsy; or
 - 3.3.3.2 The qualifying patient has a chronic or debilitating disease or medical condition where they have failed treatment involving 1 or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; severe, painful and persistent muscle spasms.
 - 3.3.4 Patients under the age of 18 will have distinctive identifying banner on their patient identification card limiting the patient to marijuana oil purchases only.
 - 3.3.5 Responsible Party's for qualifying patients under the age of 18 will be issued an identification card with the same 10-digit alphanumeric identifier provided on the patient card issued to the minor in question.

17 DE Reg. 738 (01/01/14)

4.0 Designated Caregiver Registry Identification Card Application Requirements

- 4.1 The Department shall issue a registry identification card to a primary caregiver applicant for the purpose of managing the well-being of one to five qualified patients, including themselves if caregiver is a qualified patient, in response to the requirements of this rule upon the completion and approval of the primary caregiver application form, available from the medical marijuana program, and a non-refundable application fee, in the form of a personal check or a cashier's check made out to "Division of Public Health, Medical Marijuana Program". In order for a registry identification card to be obtained and processed, the following information shall be submitted to the medical marijuana program:
 - 4.1.1 birth certificate verifying that the applicant is at least (21) years of age unless the person is the parent or legal guardian of a minor who is a qualifying patient;
 - 4.1.2 a reasonable xerographic copy of the applicant's Delaware license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; State of Delaware issued identification card must be available for inspection/verification.
 - 4.1.3 written approval by the qualified patient(s) authorizing responsibility for managing the well-being of a qualified patient(s) with respect to the use of marijuana;
 - 4.1.4 the name(s), address(es), telephone number(s) and date of birth of the qualified patient(s);
 - 4.1.5 the name, address and telephone number for each of the qualified patient's physicians;

- 4.1.6 the name, and address of the applicant as they appear on the applicant's government issued ID card, telephone number of the applicant; and
- 4.1.7 the applicant's signature and date.
- 4.2 Designated caregiver application requirements:
 - 4.2.1 Criminal history screening requirements:
 - 4.2.1.1 All designated caregiver applicants are required to consent to a nationwide and statewide criminal history screening background check. All applicable application fees associated with the nationwide and statewide criminal history screening background check shall be paid by the primary caregiver applicant.
 - 4.2.1.2 Individuals convicted of an excluded felony offense, as described in the definitions Section 2.0, and 16 **Del.C.** §4902A(7) are prohibited from serving as a designated caregiver. The applicant and qualified patient shall be notified by registered mail of his or her disqualification from being a designated caregiver.

17 DE Reg. 738 (01/01/14)

5.0 Registry Identification Cards

- 5.1 Department inquiry:
 - 5.1.1 The Department may verify information on each application and accompanying documentation by the following methods:
 - 5.1.1.1 contacting each applicant by telephone, mail, or if proof of identity is uncertain, the Department shall require a face-to-face meeting and the production of additional identification materials
 - 5.1.1.2 contacting the Delaware Division of Professional Regulation to verify that the physician is licensed to practice medicine in Delaware and is in good standing; and
 - 5.1.1.3 contacting the physician to obtain further documentation that the applicant's medical diagnosis and medical condition qualify the applicant for enrollment in the medical use marijuana program.
 - 5.1.2 Upon verification of the information contained in an application submitted in response to this subsection, the Department shall approve or deny an application within 45 calendar days of receipt.
- 5.2 Department registry identification card: The Department shall issue a registry identification card within 30 calendar days of approving an application. A registry identification card shall contain a 10-digit alphanumeric identification, maintained by the Department, which identifies the qualified patient or primary caregiver. Unless renewed at an earlier date, suspended or revoked, or if the physician stated in the written certification that the qualifying patient would benefit from marijuana until a specified earlier date, a registry identification card shall be valid for a period of one year from the date of issuance and shall expire at midnight on the day indicated on the registry identification card as the expiration date.
- 5.3 Supplemental requirement:
 - 5.3.1 A registered qualifying patient or registered designated caregiver who possesses a registry identification card shall notify the Department of any of the following within 10 calendar days of the change. An extension shall be granted by the medical marijuana program upon the showing of good cause.
 - 5.3.1.1 a change in card holder's name or address,
 - 5.3.1.2 knowledge of a change that would render the patient no longer qualified to participate in the program, such as a cure of the debilitating condition causing the need for Medical Marijuana,
 - 5.3.1.3 knowledge of a change that renders the patient's physician no longer a qualified "physician" as defined in 2.0 of these regulations,
 - 5.3.1.4 knowledge of a change that renders the patient's caregiver no longer eligible as defined in these regulations.
 - 5.3.2 Before a registered qualifying patient changes his or her designated caregiver, the qualifying patient must notify the Department in writing.
 - 5.3.3 If a cardholder loses his or her registry identification card, he or she shall notify the Department in writing within 10 days of becoming aware the card has been lost. Upon notification, the Department shall issue a new registry identification card. Unless documentation in the initial application has changed, the qualified patient or designated caregiver shall not be required to submit a new application.
 - 5.3.4 When a cardholder notifies the Department of items listed in Section 5.3 but remains eligible, the Department shall issue the cardholder a new registry identification card with a new random 10-digit alphanumeric identification number within 10 days of receiving the updated information and the cardholder shall pay a \$20 fee. If the person notifying the Department is a registered qualifying patient, the

Department shall also issue his or her registered designated caregiver, if any, a new registry identification card within 10 days of receiving the updated information.

5.3.5 If a registered qualifying patient ceases to be a registered qualifying patient or changes his or her registered designated caregiver, the Department shall promptly notify the designated caregiver by legal process server. The registered designated caregiver's protections under this chapter as to that qualifying patient shall expire 15 days after notification by the Department.

5.3.6 A cardholder who fails to make a notification to the Department that is required by Section 5.3 is subject to a civil infraction, punishable by a penalty of no more than \$150.00 and is also subject to the immediate revocation of the registry identification card and all lawful privileges provided under the act.

5.3.7 If the registered qualifying patient's certifying physician notifies the Department in writing that either the registered qualifying patient has ceased to suffer from a debilitating medical condition or that the physician no longer believes the patient would receive therapeutic or palliative benefit from the medical use of marijuana, the card shall become null and void. However, the registered qualifying patient shall have 15 days to dispose of the patient's marijuana.

5.3.8 When a registered qualifying pediatric patient passes their 18th birthday, they may request a new patient card releasing them from the pediatric restrictions. The new patient ID Card will be issued at the card replacement cost \$20 and maintain the original expiration date.

5.4 Registry identification card application denial: The DHSS Secretary or designee shall deny an application if the applicant fails to provide the information required, if the Department determines that the information provided is false, or if the patient does not have a debilitating medical condition eligible for enrollment in the program, as determined by the DHSS Secretary. A person whose application has been denied shall not reapply for six months from the date of the denial, unless otherwise authorized by the Department, and is prohibited from all lawful privileges provided by this rule and act.

5.4.1 The Department shall deny an application or renewal of a qualifying patient's registry identification card if the applicant:

5.4.1.1 did not provide the required information and materials;

5.4.1.2 previously had a registry identification card revoked; or

5.4.1.3 provided false or falsified information.

5.4.2 The Department shall deny an application or renewal for a designated caregiver chosen by a qualifying patient whose registry identification card was granted if:

5.4.2.1 the designated caregiver does not meet the requirements of Section 4.2;

5.4.2.2 the applicant did not provide the information required;

5.4.2.3 the designated caregiver previously had a registry identification card revoked; or

5.4.2.4 the applicant or the designated caregiver provides false or falsified information.

5.4.3 The Department shall notify the qualifying patient who has designated someone to serve as his or her designated caregiver if a registry identification card will not be issued to the designated caregiver.

5.4.4 Denial of an application or renewal is considered a final Department action, subject to judicial review. Jurisdiction and venue for judicial review are vested in the Superior Court.

5.5 Registry identification card renewal application: Each registry identification card issued by the Department is valid in accordance to Section 5.2. A qualified patient or primary caregiver shall apply for a registry identification card renewal no less than 45 calendar days prior to the expiration date of the existing registry identification card in order to prevent interruption of possession of a valid (unexpired) registry identification card.

5.6 Non-transferable registration of registry identification card: A registry identification card shall not be transferred, by assignment or otherwise, to other persons or locations. Any attempt shall result in the immediate revocation of the registry identification card and all lawful privileges provided by this rule and act.

5.7 Automatic expiration of registry identification card by administrative withdrawal: Upon request the qualified patient or designated caregiver shall discontinue the medical marijuana program by an administrative withdrawal. A qualified patient or designated caregiver that intends to seek an administrative withdrawal shall notify the licensing authority in writing no less than 30 calendar days prior to withdrawal.

17 DE Reg. 738 (01/01/14)

6.0 Addition of Debilitating Medical Conditions

6.1 Any citizen may petition the Department to add conditions or treatments to the list of debilitating medical conditions listed in 16 Del.C. §4902A(3).

- 6.2 The Department shall not add a condition or treatment to the list of debilitating medical conditions unless it finds that (1) the medical condition or treatment is debilitating and (2) marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition or treatment.
- 6.3 Contents of the petition: In connection with any petition to add conditions or treatments to the list of debilitating medical conditions listed in 16 **Del.C.** §4902A(3), a petitioner shall provide the following information to the Department:
- 6.3.1 The extent to which the condition is generally accepted by the medical community and other experts as a valid, existing debilitating medical condition;
 - 6.3.2 If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;
 - 6.3.3 The extent to which the condition or treatments cause severe suffering, such as severe or chronic pain or severe nausea or vomiting, or otherwise severely impair the patient's ability to carry on activities of daily living;
 - 6.3.4 The ability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition or treatment;
 - 6.3.5 The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition or treatment; and
 - 6.3.6 Letters of support from physicians or other licensed health care professionals knowledgeable about the condition or treatment.
- 6.4 Evaluation of a petition
- 6.4.1 Upon review of materials submitted in response to Section 6.3 above, the Division of Public Health (DPH) shall make a determination as to whether the petition has merit.
 - 6.4.2 A petition will be determined to have merit if it contains all of the material required in Section 6.3 above and the debilitating condition that is the subject of the petition has not been considered through this process in the prior two years, unless significant, generally accepted, scientific discoveries have been made that are substantially likely to reverse the prior decision.
 - 6.4.3 A decision that a petition does not have merit will be made in writing, stating the reason(s) it has been determined not to have merit and that it is the final decision, subject to judicial review.
 - 6.4.4 A final decision on a petition determined to have merit will be made within 180 days of receipt of the petition in response to the following process.
 - 6.4.4.1 DPH will post the complete petition on the Department's website for a 60-day public comment period.
 - 6.4.4.2 DPH will post notice of a public hearing no fewer than 10 days prior to the public hearing
 - 6.4.4.3 DPH will hold a public hearing within the 60-day public comment period.
 - 6.4.4.4 After the public hearing and closure of the 60-day public comment period, DPH will review the petition and comments. During this review, DPH may conduct additional research, including consultation with additional experts.
 - 6.4.4.5 DPH will draft a written decision on whether to grant the petition and add the debilitating medical condition for review and ultimate decision by the Department Secretary. This written decision will be detailed enough to provide the specific grounds and references to support the decision. The Department Secretary will issue the final decision on the petition.
 - 6.4.4.6 If the petition to add a debilitating medical condition is granted, draft regulations adding the condition to Section 2.0 will be drafted and published in response to the Administrative Procedures Act Process.
- 6.5 The approval or denial of any petition is a final decision of the Department subject to judicial review. Jurisdiction and venue are vested in the Superior Court.

17 DE Reg. 738 (01/01/14)

7.0 Registration and operation of compassion centers

- 7.1 Requirements for operation of a compassion center.
- 7.1.1 General requirements
 - 7.1.1.1 No person shall operate a compassion center without a Department issued certificate of registration. The application and renewal requirements for a certificate of registration are in Sections 7.6 and 7.10 of these regulations.

- 7.1.1.2 A compassion center shall be operated on a not-for-profit basis. A compassion center need not be recognized as a tax-exempt organization by the Internal Revenue Service and is not required to incorporate in response to Title 8; however, a compassion center shall maintain appropriate documentation of its not-for-profit status, and such documentation shall be available for inspection in response to Section 7.2.7 of these Regulations.
- 7.1.1.3 A compassion center shall not acquire, possess, cultivate, manufacture, deliver, transfer, transport, supply or dispense marijuana for any purpose except to assist registered qualifying patients with the medical use of marijuana directly or through the qualifying patient's registered designated caregiver.
- 7.1.1.4 Use of pesticides is prohibited:
 - 7.1.1.4.1 There are no pesticides authorized for use on marijuana; as such, a compassion center shall not apply pesticides in the cultivation of marijuana.
 - 7.1.1.4.2 Prohibited pesticides include but are not limited to the following:
 - 7.1.1.4.2.1 Organochlorines;
 - 7.1.1.4.2.2 Organophosphates;
 - 7.1.1.4.2.3 Cargamates; and
 - 7.1.1.4.2.4 Insecticidal, fungicidal or growth regulatory compounds.
- 7.1.2 Location of a compassion center: A compassion center shall not be located within 1,000 feet of the property line of a preexisting public or private school.
- 7.1.3 Bylaws
 - 7.1.3.1 A compassion center shall, as part of its initial application, provide to the Department a true, correct, and current copy of its bylaws, and shall maintain such bylaws in accordance with the Act and these regulations.
 - 7.1.3.2 The bylaws of a compassion center shall include at a minimum:
 - 7.1.3.2.1 the ownership structure of the compassion center;
 - 7.1.3.2.2 the composition of the board of directors; and
 - 7.1.3.2.3 such provisions relative to the disposition of revenues to establish and maintain the not-for-profit character of the compassion center.
- 7.1.4 Maintenance of accurate books and records
 - 7.1.4.1 Registered compassion centers shall keep detailed financial reports of proceeds and expenses.
 - 7.1.4.2 Registered compassion centers shall maintain all inventory, sales and financial records in accordance with generally accepted accounting principles ("GAAP").
 - 7.1.4.3 The Department or an audit firm contracted by the Department shall at all times have access to all books and records kept by any compassion center.
- 7.1.5 Disposal of Unusable Marijuana
 - 7.1.5.1 The medical marijuana inventory system must be updated immediately when a plant is pulled out of inventory for destruction. The plant number, date and reason must be recorded. This information must be available for auditing by the department.
 - 7.1.5.2 Medical marijuana waste must be stored, secured, and managed in accordance with these regulations and approved operations manual procedures. Medical marijuana waste must be made unusable prior to the waste leaving a registered facility.
 - 7.1.5.3 Liquid waste from medical marijuana facilities shall be disposed of in compliance with the applicable County statutes and regulations including the International Plumbing Code.
 - 7.1.5.4 Medical marijuana waste shall be rendered unusable through grinding and incorporating the medical marijuana waste with non-consumable, solid wastes listed below such that the resulting mixture is at least fifty percent non-marijuana waste:
 - 7.1.5.4.1 Paper waste.
 - 7.1.5.4.2 Plastic waste.
 - 7.1.5.4.3 Cardboard waste.
 - 7.1.5.4.4 Food waste.
 - 7.1.5.4.5 Soil.
 - 7.1.5.4.6 Grease or other compostable oil waste.
 - 7.1.5.4.7 Other wastes approved by the Division of Public Health, Health Systems Protection Section that will render the medical marijuana waste unusable.

7.1.5.5 After the medical marijuana waste is made unusable, then the solid waste shall be:

- 7.1.5.5.1 Disposed of as a solid waste at a solid waste site and disposal facility that has a Certificate of Designation from the local governing body.
- 7.1.5.5.2 Deposited at a compost facility that has a Certificate of Designation from the Department of Natural Resources and Environmental Control (DNREC), or
- 7.1.5.5.3 Composted on-site at a facility owned by the generator and operated in compliance with applicable County statutes and regulations.

7.2 Security requirements: A compassion center shall implement appropriate security and safety measures to deter and prevent the unauthorized entrance into areas containing marijuana and the theft of marijuana. Such measures shall include the following:

7.2.1 Exterior of premises: With respect to the exterior of a compassion center:

- 7.2.1.1 Access from outside the premises shall be kept to a minimum and be well controlled.
- 7.2.1.2 The outside perimeter of the premises shall be well lighted.
- 7.2.1.3 Entry into any area(s) where marijuana is held shall be limited to authorized personnel.

7.2.2 Alarm system:

7.2.2.1 A compassion center shall have a fully operational security alarm system at each authorized physical address that will provide suitable protection against theft and diversion. For the purpose of these regulations, a fully operational security alarm system shall include:

- 7.2.2.1.1 immediate automatic or electronic notification to alert local or municipal law enforcement agencies to an unauthorized breach of security at the compassion center or at any other authorized physical address;
- 7.2.2.1.2 immediate automatic or electronic notification to local or municipal public safety personnel of a loss of electrical support backup system; and
- 7.2.2.1.3 when appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

7.2.2.2 A compassion center shall conduct a maintenance inspection/test of the alarm system for each authorized location at intervals not to exceed 30 days from the previous inspection/test. A compassion center shall promptly make all necessary repairs to ensure the proper operation of the alarm system.

7.2.2.3 In the event of a failure of the security system, due to loss of electrical support or mechanical malfunction, that is expected to exceed an eight hour period, a compassion center shall:

- 7.2.2.3.1 within 24 hours of discovery of the event, notify the Department by telephone; and
- 7.2.2.3.2 provide alternative security measures approved by the Department or close the authorized physical address(es) impacted by the failure/malfunction until the security alarm system has been restored to full operation.

7.2.2.4 A compassion center shall maintain documentation in an auditable form for a period of at least 24 months after the event for:

- 7.2.2.4.1 all maintenance inspections/tests conducted in response to Section 7.2.2.2 of these regulations, and any servicing, modification or upgrade performed on the security alarm system. The record shall include, as a minimum, the date of the action, a summary of the action(s) performed and the name, signature and title of the individual who performed the action(s);
- 7.2.2.4.2 any alarm activation or other event which requires response by public safety personnel; and
- 7.2.2.4.3 any unauthorized breach(es) of security.

7.2.3 Video surveillance: A compassion center shall provide an appropriate video surveillance system that includes the following areas and access to recorded surveillance.

- 7.2.3.1 Video surveillance should record access areas, customer service areas, growing areas, and anywhere the marijuana is handled, to include processing and packaging areas.
- 7.2.3.2 Video footage will be digitally recorded and held for an appropriate time period consistent with the Division of Public Health's Records Retention Policy.
- 7.2.3.3 A compassion center shall provide the Department with access to the video 24-hours a day, seven days a week through a secure internet connection.

7.2.4 Inventory controls

7.2.4.1 Coding and computer interface: A compassion center shall:

- 7.2.4.1.1 employ a bar coding inventory control system to track batch, strain and amounts of marijuana in inventory and amounts sold, to include patients' card registration numbers.
- 7.2.4.1.2 be responsible for developing and hosting a secure computer interface to receive patient card user data from the Department.
- 7.2.4.2 Storage of marijuana: A compassion center shall ensure that usable marijuana is stored in a locked area with adequate security. For purpose of these regulations "adequate security," at a minimum, should be assessed, established and maintained based on:
 - 7.2.4.2.1 the quantity of usable marijuana that will be kept on hand at each authorized location;
 - 7.2.4.2.2 the compassion center's inventory system for tracking and dispensing usable marijuana;
 - 7.2.4.2.3 the number of principal officers, board members, agents, volunteers or employees who have or could have access to the usable marijuana;
 - 7.2.4.2.4 the geographic location of the compassion center (i.e.: high-crime or low-crime area);
 - 7.2.4.2.5 the scope and sustainability of the alarm system; and
 - 7.2.4.2.6 the root cause analysis of any breach of security and/or inventory discrepancy for usable marijuana at that location.
- 7.2.5 Comprehensive and monthly inventories
 - 7.2.5.1 A compassion center shall:
 - 7.2.5.1.1 notify the Department and local law enforcement within 24 hours any time there is a suspected loss of marijuana and shall cooperate fully with any investigation into the suspected loss.
 - 7.2.5.1.2 conduct an initial comprehensive inventory of all medical marijuana, including usable marijuana available for dispensing, mature marijuana plants and unusable marijuana, at each authorized location on the date the compassion center first dispenses medical marijuana.
 - 7.2.5.1.3 conduct the comprehensive inventory required by Section 7.2.5 of these regulations at intervals not to exceed 24 months from the date of the previous comprehensive inventory.
 - 7.2.5.1.4 conduct a monthly inventory review of stored, usable marijuana.
 - 7.2.5.2 If an inventory conducted in response to Section 7.2.5.1 of these regulations identifies a discrepancy, the Department and appropriate local law enforcement authorities will be notified of the discrepancy within 24 hours of discovery of the event.
 - 7.2.5.3 Documentation of all inventories conducted in response to Section 7.2.5.1 of these regulations shall include, as a minimum, the date of the inventory, a summary of the inventory findings and the name, signature and title of the individual(s) who conducted the inventory.
- 7.2.6 Maximum amount of compassion center inventory. A registered compassion center:
 - 7.2.6.1 ~~shall possess no more than 150 marijuana plants irrespective of the stages of growth~~ shall grow an amount of marijuana sufficient to meet the qualifying patient population demands as determined by the Division.
 - 7.2.6.2 shall possess no more than ~~1,500~~ 2,000 ounces of usable marijuana regardless of formulation.
 - 7.2.6.3 may not purchase usable marijuana or mature marijuana plants from any person other than another registered compassion center.
- 7.2.7 Inspection. Compassion centers are subject to random inspection by the Department's Office of Medical Marijuana.
 - 7.2.7.1 During an inspection, the Department may review the compassion center's confidential records, including its financial and dispensing records, which may track transactions according to qualifying patients' registry identification numbers to protect their confidentiality and its security protocols.
 - 7.2.7.2 The Department will review the facility to ensure compliance with Section 7.2 and Section 7.3 of these regulations.
 - 7.2.7.3 The Department will inspect the facility for the presence of pesticides listed in Section 7.1.1.4, fungus and molds.
 - 7.2.7.4 The Department may collect samples for random quality sampling by a laboratory selected by the Department.
 - 7.2.7.4.1 Sample results will be compared to compassion center test results.
 - 7.2.7.3.2 The compassion center will be invoiced for the cost of random sampling testing.
- 7.2.8 Dispensing marijuana.
 - 7.2.8.1 Design and security features of medical marijuana containers

7.2.8.1.1 Marijuana shall be dispensed in sealed, tamperproof containers clearly identified as having been issued by the compassion center and that meet the requirements in Section 7.3.10 of these regulations.

7.2.8.1.2 Patients and designated caregivers should receive written instruction that the marijuana shall remain in this container when it is not being prepared for ingestion or being ingested.

7.2.8.2 No marijuana shall be dispensed unless or until the patient or caregiver identification card has been verified as valid in the computer system identified in Section 7.2.4.1.2 of these regulations.

7.2.8.3 Maximum amount of usable marijuana to be dispensed.

7.2.8.3.1 A compassion center or principal officer, board member, agent, volunteer or employee of a compassion center

7.2.8.3.1.1 shall not dispense, deliver or otherwise transfer marijuana to a person other than a qualifying patient ~~who has designated the compassion center as a primary caregiver~~ or to such patient's other primary caregiver.

7.2.8.3.1.2 shall not dispense more than three ounces of usable marijuana to a qualifying patient directly or through a qualifying patient's caregiver during a 14 day period.

7.2.8.3.1.3 shall not dispense an amount of usable marijuana to a qualifying patient or a qualifying patient's caregiver that the compassion center principal officer, board member, agent, volunteer or employee knows would cause the recipient to possess more marijuana than is permitted under the Act or these regulations.

7.2.8.3.1.4 shall dispense pediatric medical marijuana oils as described in Section 2.0 of these regulations to qualified patients under the age of 18 years. Patients under the age of 18 are restricted from purchasing products other than pediatric medical marijuana oil.

7.2.8.3.2 In addition to any other penalties that may be applicable under the Act or these regulations, any person found to have violated Section 7.2.8 of these regulations is not eligible to be an employee, agent, principal officer or board member of any compassion center and such person's registry identification card shall be immediately revoked.

7.3 Operations manual. A compassion center shall, as part of its initial application, provide to the Department a true, correct and current copy of its operating manual, and shall maintain such operating manual in accordance with the Act and these regulations. Such manual shall include, as a minimum, the following requirements:

7.3.1 procedures for the oversight of the compassion center including, but not limited to, documentation of the reporting and management structure of the compassion center;

7.3.2 procedures for safely dispensing medical marijuana to registered qualifying patients or their registered primary caregiver;

7.3.3 procedures to ensure accurate record keeping, including protocols to ensure that quantities purchased do not suggest re-distribution;

7.3.4 employee security policies;

7.3.5 safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;

7.3.6 personal safety and crime prevention techniques;

7.3.7 a job description or employment contract developed for all employees and a volunteer agreement for all volunteers which includes duties, responsibilities, authority, qualification and supervision;

7.3.8 the compassion center's alcohol and drug free work place policy;

7.3.9 a description of the compassion center's outreach activities to registered qualifying patients or their registered primary caregiver, which shall as a minimum include:

7.3.9.1 providing each new registered patient who visits the compassion center with frequently asked questions, designed by the Department, that explain the limitations on the right to use medical marijuana under state law;

7.3.9.2 ingestion options of usable marijuana provided by the compassion center;

7.3.9.3 safe smoking techniques that shall be provided to registered qualifying patients; and

7.3.9.4 potential side effects and how this information shall be communicated.

7.3.10 a description of the packaging of the useable marijuana that the compassion center shall be utilizing which shall, as a minimum, include:

7.3.10.1 the name of the strain, batch, and quantity;

7.3.10.2 the statement "this product is for medical use only, not for resale;" and

- 7.3.10.3 details indicating (1) the medical marijuana is free of contaminants and (2) the levels of active ingredients in the product.
- 7.3.11 a description of the documentation that will accompany a registered compassion center agent when transporting marijuana on behalf of the registered compassion center. In response to 16 **Del.C.** §4918A(b), the documentation must specify, at least, the amount of marijuana being transported, the date the marijuana is being transported, the registry identification number of the registered compassion center, and a contact number to verify that the marijuana is being transported on behalf of the registered compassion center.
- 7.3.12 detailed procedures regarding the testing of medical marijuana. As part of its initial application, a compassion center shall provide to the Department detailed procedures regarding the testing of medical marijuana, and shall adhere to such procedures in connection with the operation of the compassion center. Such procedures shall include a description of how the marijuana will be tested, including:
 - 7.3.12.1 whether the testing will be conducted in house or through a contracted facility;
 - 7.3.12.2 how marijuana will be transported securely in connection with such testing;
 - 7.3.12.3 what tests are conducted, including what testing procedures are used;
 - 7.3.12.4 how results are tracked and how samples are disposed; and
 - 7.3.12.5 the selection process and the number of samples tested.
- 7.4 Required training. Each compassion center shall develop, implement and maintain on the premises an on-site training curriculum, or enter into contractual relationships with outside resources capable of meeting employee, agent and volunteer training needs. Each employee, agent or volunteer, at the time of initial appointment, shall receive, as a minimum, training in the following:
 - 7.4.1 professional conduct, ethics, and state and federal laws regarding patient confidentiality;
 - 7.4.2 informational developments in the field of medical use of marijuana;
 - 7.4.3 The proper use of security measures and controls that have been adopted; and
 - 7.4.4 Specific procedural instructions for responding to an emergency, including robbery or violent accident.
- 7.5 Personnel
 - 7.5.1 Records: Each compassion center shall maintain
 - 7.5.1.1 a personnel record for each employee, agent or volunteer for a period of at least six months after termination of the individual's affiliation with the compassion center. The record shall include, as a minimum, the following:
 - 7.5.1.1.1 an application for employment or to volunteer;
 - 7.5.1.1.2 a record of any disciplinary action taken;
 - 7.5.1.1.3 documentation of all required training. Documentation shall include a signed statement from the individual indicating the date, time and place of said training and topics discussed, including the name and title of presenters;
 - 7.5.1.2 a record of the source of any funds that will be used to open or maintain the compassion center, including the name, address, and date of birth of any investor contributing more than \$5,000; and
 - 7.5.1.3 a record of any instances in which a business or not-for-profit that any of the prospective board members managed or served on the board of was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding.
 - 7.5.2 Registry identification cards and background checks for principal officers, board members, agents, volunteers or employees of a compassion center.
 - 7.5.2.1 In response to the requirements of this rule, and upon the approval of the submitted application, the Department shall issue a registry photo identification card to each principal officer, board member, agent, volunteer or employee of a compassion center who is associated with the compassion center and meets the requirements under these regulations. In order for a registry identification card to be obtained, the following items shall be submitted to the medical marijuana program.
 - 7.5.2.1.1 birth certificate verifying that the applicant is at least 21 years of age;
 - 7.5.2.1.2 a reasonable xerographic copy of the applicant's Delaware license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; identification card must be available for inspection/verification;
 - 7.5.2.1.3 a written and signed statement from an officer or executive staff member of the compassion center stating that the applicant is associated with the compassion center and in what capacity;

- 7.5.2.1.4 the name, address and telephone number of the applicant;
- 7.5.2.1.5 the name, address and telephone number of the compassion center with which the agent is associated;
- 7.5.2.1.6 the applicant's signature and date
- 7.5.2.1.7 a non-refundable, non-returnable application or renewal fee of \$125 in the form of a check made out to "Division of Public Health, Medical Marijuana Program."
- 7.5.2.2 In response to 16 **Del.C.** §§4914A and 4915A, each principal officer, board member, agent, volunteer or employee of a compassion center shall consent to a full nationwide and statewide criminal history screening background check.
 - 7.5.2.2.1 Each applicant shall submit a full State Bureau of Identification (SBI) criminal history screening check and a full nationwide criminal history screening check to demonstrate compliance with the eligibility requirements of these regulations.
 - 7.5.2.2.2 All applicable fees associated with the required criminal history screening background checks shall be paid by the compassion center or the applicant.
 - 7.5.2.2.3 In response to 16 **Del.C.** §4919A(n), individuals convicted of an excluded felony offense, as described in the definitions Section 2.0, and 16 **Del.C.** §4902A(7), within five years from the date of application, are prohibited from being a compassion center agent.
- 7.5.2.3 The Department may verify information on each application and the accompanying documentation as set forth in section 5.1 of these regulations.
- 7.5.2.4 The Department shall notify the compassion center in writing of the purpose for denying the registry identification card in accordance with § 4918A of the Act. The DHSS Secretary or designee shall deny an application if the applicant fails to provide the information required or if the Department determines that the information provided is false. Denial of an application or renewal is considered a final Department action, subject to judicial review. Jurisdiction and venue for judicial review are vested in the Superior Court.
- 7.5.2.5 The Department shall issue each principal officer, board member, agent, volunteer or employee of a compassion center a registry identification card within 30 days of receipt of the information required by Section 7.5.2.1 and Section 7.5.2.2. The registry identification card shall contain such information as set forth in §4911A of the Act and Section 7.5.2 of these regulations.
- 7.5.2.6 Each compassion center shall notify the Department in writing within ten days of when a principal officer, board member, agent, volunteer or employee ceases to work at the compassion center. The individual's registry identification card shall be deemed null and void and the individual shall be liable for any other penalties that may apply to the individual's nonmedical use of marijuana.
- 7.5.3 Expiration date of registry identification cards. The registry identification card of a principal officer, board member, agent, volunteer or employee shall expire one year after its issuance, or upon the expiration of the compassion center's registration certificate, whichever comes first.
- 7.6 Application for operation of a compassion center. Applicants shall only be accepted during an open application period announced by the Department and shall include the following items:
 - 7.6.1 a non-refundable application fee, made payable to the Division of Public Health, Medical Marijuana Program, in the amount of \$5,000;
 - 7.6.2 the proposed legal name, articles of incorporation and bylaws of the compassion center;
 - 7.6.3 the proposed physical address(es) of the compassion center, including any additional address(es) to be used for the secure cultivation of medical marijuana, and with the following details:
 - 7.6.3.1 if precise addresses are known, evidence of compliance to the following rules shall be included:
 - 7.6.3.1.1 compliance to the local zoning laws for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana;
 - 7.6.3.1.2 evidence that all of the physical addresses identified in this section are not located within 1,000 feet of a property line of a preexisting public or private school;
 - 7.6.3.2 if precise addresses have not been determined, identification of the general location(s) where it would be sited, and when it would be established;
 - 7.6.4 a description of the enclosed, locked facility, meeting all requirements of section 7.2 that would be used in the cultivation of marijuana, including steps to ensure that the marijuana production shall not be visible from the street or other public areas;
 - 7.6.5 evidence of the compassion center's not-for-profit status, which can be:
 - 7.6.5.1 documentation of recognition as a tax-exempt organization by the United States Internal Revenue Service; or

- 7.6.5.2 other written materials which will allow the Department to determine the compassion center's ability to comply with the revenue criteria contained in 16 **Del.C.** §4914A and §4915A.
- 7.6.6 the name, address, and date of birth of each principal officer and board member of the compassion center;
- 7.6.7 a description of proposed security and safety measures which demonstrate compliance with Section 7.2 of these regulations;
- 7.6.8 a draft operations manual which demonstrates compliance with Section 7.3 of these regulations;
- 7.6.9 an example of the design and security features of medical marijuana containers which demonstrates compliance with Section 7.2.8 of these regulations;
- 7.6.10 a list of all persons or business entities having direct or indirect authority over the management or policies of the compassion center;
- 7.6.11 a list of all persons or business entities having 5.0% or more ownership in the compassion center, whether direct or indirect and whether the interest is in profits, land or building, including owners of any business entity which owns all or part of the land or building, and;
- 7.6.12 the identities of all creditors holding a security interest in the premises, if any.
- 7.7 Complete application required. Only applications which the Department has determined to be complete (i.e. adequately addresses all requirements in these regulations and 16 **Del.C.** §§4914A and 4915A) shall be eligible for review in response to §7.8 of these regulations.
- 7.8 Compassion center application review criteria. The Department shall evaluate applications for a compassion center registration certificate using an impartial and numerically scored competitive bidding process developed by the Department in accordance with 16 **Del.C.** §4914A(b) and these regulations. The Department shall consider the following criteria:
 - 7.8.1 documentation of not-for-profit status, consistent with §7.6.5 of these regulations;
 - 7.8.2 the suitability of the proposed location or locations, including but not limited to compliance with any local zoning laws and the geographic convenience to patients from throughout the State of Delaware to compassion centers if the applicant were approved;
 - 7.8.3 the principal officer and board members' character and relevant experience, including any training or professional licensing related to medicine, pharmaceuticals, natural treatments, botany, or marijuana cultivation and preparation and their experience running business or not-for-profit entities;
 - 7.8.4 the proposed compassion center's plan for operations and services, including its staffing and training plans, whether it has sufficient capital to operate, and its ability to provide an adequate supply and variety of medical marijuana and medical marijuana based products to the registered patients in the State;
 - 7.8.5 the sufficiency of the applicant's plans for record keeping;
 - 7.8.6 the sufficiency of the applicant's plans for safety, security, and the prevention of diversion, including proposed locations and security devices employed;
 - 7.8.7 the applicant's plan for making medical marijuana available on an affordable basis to registered qualifying patients enrolled in Medicaid or receiving Supplemental Security Income or Social Security Disability Insurance;
 - 7.8.8 the applicant's plan for safe and accurate packaging and labeling of medical marijuana, which shall include, without limitations, these minimum requirements for packaging and labeling:
 - 7.8.8.1 the name of the strain, batch, and quantity of the medical marijuana;
 - 7.8.8.2 a statement providing that "this product is for medical use only, not for resale";
 - 7.8.8.3 details indicating the medical marijuana is free of contaminants; and
 - 7.8.8.4 details indicating the levels of active ingredients in the product;
 - 7.8.9 the applicant's plan for testing medical marijuana for contaminants and potency of active ingredients; and
 - 7.8.10 the applicant's ability to grow marijuana without use of pesticides.
- 7.9 Issuance of a registration certificate authorizing operation of a compassion center. When an applicant to operate a compassion center is notified that the Department has approved its application, it shall submit the following additional items to the Department before the registration certificate authorizing operation of a compassion center will be issued.
 - 7.9.1 a certification fee, made payable to the Division of Public Health, Medical Marijuana Program, in the amount of \$40,000;
 - 7.9.2 the legal name, articles of incorporation, and bylaws of the compassion center;
 - 7.9.3 the physical address of the compassion center and any additional address(es) to be used for the secure cultivation of marijuana, including:
 - 7.9.3.1 evidence demonstrating the following:

- 7.9.3.1.1 compliance with all local zoning laws for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana; and
 - 7.9.3.1.2 that none of the physical addresses identified in Section 7.9.3 of these regulations are located within 1,000 feet of the property line of preexisting public or private schools;
 - 7.9.3.2 it is not necessary to resubmit any information provided in response to Section 7.6.3.1 of these regulations unless there has been a change in that information;
 - 7.9.4 any updates to previously submitted information including, but not limited to, information about officers, principals, board members, agents, employees, and compliance with Sections 7.2 and 7.3 of these regulations;
 - 7.9.5 a current certificate of occupancy, or equivalent document, to demonstrate compliance with the provisions of the State Fire Code for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana.
- 7.10 Expiration, termination, or renewal of a registration certificate authorizing operation of a compassion center.
- 7.10.1 Expiration: A compassion center's registration shall expire two years after its registration certificate is issued. The compassion center may submit a renewal application at any time beginning 90 days prior to the expiration of its registration certificate. Such renewal application must be submitted a minimum of 30 days prior to the expiration of its registration certificate to avoid suspension of the certificate.
 - 7.10.2 Renewal: The Department shall grant a compassion center's renewal application within 30 days of its submission if the following conditions are all satisfied.
 - 7.10.2.1 The compassion center submits materials required under Section 7.9 of these regulations, including a \$40,000 fee, which shall be refunded if the renewal application is rejected;
 - 7.10.2.2 The Department has not ever suspended the compassion center's registration for violations of the Act or these regulations;
 - 7.10.2.3 Inspections conducted pursuant to the Act and these Regulations do not raise any serious concerns about the continued operation of the registered compassion center applying for renewal.
 - 7.10.2.4 The applicant continues to meet all of the requirements for the operation of a compassion center as set forth in the Act and in these regulations.
 - 7.10.3 Suspension: The Department will suspend a registration certificate authorizing the operation of a compassion center, with or without notice, for any violation of an applicable law or regulation.
 - 7.10.4 Termination: Upon receipt of written notice that a registration certificate has been terminated, the compassion center has 30 business days to request, in writing, a hearing, for the purpose of review of such action. The hearing process shall follow the procedures in Section 9.4 through Section 9.13 of these regulations:
 - 7.10.4.1 A written decision will be issued by the Department within 30 days of the completion of the hearing. The decision will lift the suspension or terminate a registration certificate. The written decision will state with specificity the reasons for the decision.
 - 7.10.4.2 The termination of a registration certificate is a final decision of the Department, subject to judicial review. Jurisdiction and venue are vested in the Superior Court.
- 7.11 Non-transferable registration certificate authorizing operation of a compassion center.
- 7.11.1 A registration certificate authorizing operation of a compassion center shall not be transferred by assignment or otherwise to other persons or locations. Unless the compassion center applies for and receives an amended registration certificate authorizing operation of a compassion center, the registration certificate shall be void and returned to the Department when one or more of the following situations occur:
 - 7.11.1.1 a change in ownership of the compassion center;
 - 7.11.1.2 a change in one or more authorized physical locations; or
 - 7.11.1.3 the compassion center discontinues its operation.
 - 7.11.2 A compassion center shall provide the Department with a written notice of any change described in Section 7.11 of these regulations at least 60 days prior to the proposed effective date of the change. The Department may waive all or part of the required advance notice to address emergent or emergency situations.
 - 7.11.3 Transactions which usually do not constitute a change of ownership include the following:
 - 7.11.3.1 changes in the membership of the board of directors or board of trustees; or
 - 7.11.3.2 two or more legal entities merge and the entity to whom the registration certificate authorizing operation of a compassion center was issued survives.
 - 7.11.4 Management agreements are generally not considered a change in ownership if the entity to whom the registration certificate authorizing operation of a compassion center was issued continues to retain ultimate

authority for the operation of the compassion center; however, if the ultimate authority is surrendered and transferred from the entity to whom the registration certificate authorizing operation of a compassion center was issued to a new manager, then a change of ownership has occurred.

17 DE Reg. 738 (01/01/14)

8.0 Registration and Operation of Testing Facility Centers

- 8.1 General Requirements for Operation of a Testing Facility Center. RESERVED
- 8.2 Security Requirements: RESERVED
- 8.3 Operations Manual. RESERVED
- 8.4 Required Training. RESERVED
- 8.5 Personnel Records. RESERVED
- 8.6 Application for Operation of Testing Facility Center. RESERVED
- 8.7 Complete Application Required. RESERVED
- 8.8 Testing Facility Center Application Review Criteria. RESERVED
- 8.9 Issuance of Registration Certificate Authorizing Operation of a Testing Facility Center. RESERVED
- 8.10 Registry Identification Cards for Principal Officers, Board Members, Agents, Volunteers or Employees of a Testing Facility Center. RESERVED
- 8.11 Expiration Date. RESERVED
- 8.12 Expiration, Termination or Renewal of a Registration Certificate Authorizing Operation of a Testing Facility Center. RESERVED
- 8.13 Non-transferable Registration Certificate Authorizing Operation of a Testing Facility Center. RESERVED
- 8.14 Inspection. RESERVED

17 DE Reg. 738 (01/01/14)

9.0 Monitoring and Corrective Action

9.1 On-site visits/interviews

- 9.1.1 The Department or its designee may perform on-site interviews of a qualified patient or primary caregiver to determine eligibility for the program. The Department may enter the premises of a qualified patient or primary caregiver during business hours for purposes of interviewing a program applicant. Twenty-four (24) hours' notice will be provided to the qualified patient or primary caregiver prior to an on-site interview.
- 9.1.2 All qualified patients or primary caregivers shall provide the Department or the Department's designee immediate access to any material and information necessary for determining eligibility with these requirements.
- 9.1.3 Failure by the qualified patient or primary caregiver to provide the Department access to the premises or information may result in action up to and including the revocation of the qualified patient or primary caregiver registry identification card and referral to state law enforcement.
- 9.1.4 Any failure to adhere to these rules, documented by the Department during an interview, may result in sanction(s), including suspension, revocation, non-renewal or denial of licensure and referral to state or local law enforcement.
- 9.1.5 The Department shall refer credible criminal complaints against a qualified patient or primary a caregiver to the appropriate Delaware state or appropriate local authorities.

9.2 Corrective action:

- 9.2.1 If violations of these requirements are cited as a result of monitoring, the qualified patient or primary caregiver shall be provided with an official written report of the findings following the monitoring visit.
- 9.2.2 Unless otherwise specified by the Department, the qualified patient or primary caregiver shall correct the violation within 5 calendar days of receipt of the official written report citing the violation(s).
- 9.2.3 The violation shall not be deemed corrected until the Department verifies in writing after receiving notice of the corrective action that the corrective action is satisfactory.
- 9.2.4 If the violation has not been corrected, the Department may issue a notice of contemplated action to revoke the qualified patient's or designated caregiver's registry identification card.
- 9.2.5 Suspension of registry identification card without prior hearing: In accordance with the 16 **Del.C.** Ch. 49A, if immediate action is required to protect the health and safety of the general public, the Department may suspend the qualified patient or designated caregiver registry identification card without notice.

- 9.2.5.1 A qualified patient or primary caregiver whose registry identification card has been summarily suspended is entitled to a record review not later than 30 calendar days after the registry identification card was summarily suspended.
- 9.2.5.2 The record review requested subsequent to a summary suspension shall be conducted by the Department.
- 9.2.5.3 The Department shall conduct the record review on the summary suspension by reviewing all documents submitted by both card holder and the Department.
- 9.2.5.4 The sole issue at a record review on a summary suspension is whether the card holder's registry identification card shall remain suspended pending a final adjudicatory hearing and ruling.
- 9.2.5.5 A card holder given notice of summary suspension by the division may submit a written request for a record review. To be effective, the written request shall:
 - 9.2.5.5.1 be made within 30 calendar days, as determined by the postmark, from the date of the notice issued by the Department;
 - 9.2.5.5.2 be properly addressed to the medical marijuana program;
 - 9.2.5.5.3 state the applicant's name, address, and telephone number(s);
 - 9.2.5.5.4 provide a brief narrative rebutting the circumstances of the suspension, and
 - 9.2.5.5.5 additional documentation must be included with the request for a record review.

9.3 Summary Suspension, Revocation and Appeal Process:

- 9.3.1 Participation in the medical marijuana program by a qualified patient or primary caregiver does not relieve the qualified patient or primary caregiver from:
 - 9.3.1.1 criminal prosecution or civil penalties for activities not authorized in this rule and act;
 - 9.3.1.2 liability for damages or criminal prosecution arising out of the operation of a vehicle while under the influence of marijuana; or
 - 9.3.1.3 criminal prosecution or civil penalty for possession, distribution or transfers of marijuana or use of marijuana:
 - 9.3.1.3.1 in a school bus or public vehicle;
 - 9.3.1.3.2 on school grounds or property;
 - 9.3.1.3.3 in the workplace of the qualified patient's or primary caregiver's employment;
 - 9.3.1.3.4 at a public park, recreation center, youth center or other public place;
 - 9.3.1.3.5 to a person not approved by the Department pursuant to this rule;
 - 9.3.1.3.6 outside Delaware or attempts to obtain or transport marijuana from outside Delaware; or
 - 9.3.1.3.7 that exceeds the allotted amount of usable medical use marijuana.
- 9.3.2 Revocation of registry identification card: Violation of any provision of this rule may result in either the summary suspension of the qualified patient's or primary caregiver's registry identification card, or a notice of contemplated action to suspend or revoke the qualified patient's or primary caregiver's registry identification card, and all lawful privileges under the act.
- 9.3.3 Grounds for revocation or suspension of registry identification card, denial of renewal application for registry identification card. A registry identification card may be revoked or suspended, and a renewal application may be denied for:
 - 9.3.3.1 failure to comply with any provisions of these requirements;
 - 9.3.3.2 failure to allow a monitoring visit by authorized representatives of the Department;
 - 9.3.3.3 the discovery of repeated violations of these requirements during monitoring visits.

9.4 Request for hearing: A qualified patient or primary caregiver whose registry identification card has been summarily suspended, or who has received a notice of contemplated action to suspend or revoke, may request a hearing, in addition to a request for a record review, for the purpose of review of such action. The request for hearing shall be filed within 30 calendar days of the date the action is taken or the notice of contemplated action is received. The request shall include the following:

- 9.4.1 a statement of the facts relevant to the review of the action;
- 9.4.2 a statement of the provision of the act and the rules promulgated under the act that are relevant to the review of the action;
- 9.4.3 a statement of the arguments that the qualified patient/primary caregiver considers relevant to the review of the action; and
- 9.4.4 any other evidence considered relevant.

9.5 Hearing process:

- 9.5.1 All formal adjudicatory hearings held in response to these Regulations shall be conducted by a hearing officer duly appointed by the DHSS Secretary.
- 9.5.2 Except for telephonic hearings, hearings shall be conducted in Dover or, upon written request by an aggrieved person, in the place or area affected.
- 9.5.3 All hearings held pursuant to this section shall be open to the public.
- 9.5.4 The hearing shall be recorded on audiotape or other means of sound reproduction, or by a certified court reporter. The decision as to the type of recording shall be at the discretion of the Department.
- 9.5.5 Any hearing provided for in this rule may be held telephonically, in the interest of a speedy resolution.
- 9.5.6 The Department shall schedule and hold the hearing as soon as practicable, however; in any event no later than 60 calendar days from the date the Department receives the request for hearing. The hearing officer shall extend the 60 day time period upon motion for good cause shown or the parties shall extend the 60 day time period by mutual agreement. The Department shall issue notice of hearing, not less than 20 days prior to the hearing, which shall include:
 - 9.5.6.1 a statement of the time, place and nature of the hearing;
 - 9.5.6.2 a statement of the legal authority and jurisdiction under which the hearing is to be held;
 - 9.5.6.3 a short and plain statement of the matters of fact and law asserted;
 - 9.5.6.4 notice to any other parties to give prompt notice of issues controverted in fact or law; and
 - 9.5.6.5 all necessary telephone numbers if a telephonic hearing shall be conducted.
- 9.6 All parties shall be given the opportunity to respond and present evidence and argument on all relevant issues.
- 9.7 Record of proceeding: The record of the proceeding shall include the following:
 - 9.7.1 all pleadings, motions and intermediate rulings;
 - 9.7.2 evidence received or considered;
 - 9.7.3 a statement of matters officially noticed;
 - 9.7.4 questions and offers of proof, objections and rulings thereon;
 - 9.7.5 proposed findings and conclusions; and
 - 9.7.6 any action recommended by the hearing officer.
- 9.8 A party may request a transcription of the proceedings. The party requesting the transcript shall bear the cost of transcription.
- 9.9 Procedures and evidence:
 - 9.9.1 Any party shall be represented by a person licensed to practice law in Delaware or an individual may represent him or herself.
 - 9.9.2 The rules of evidence as applied in the courts do not apply in these proceedings. Any relevant evidence shall be admitted and such evidence shall be sufficient in itself to support a finding if the evidence is reliable, regardless of the existence of any statutory or common law rule that shall make admission of such evidence improper in a civil action. Irrelevant, immaterial or unduly repetitious evidence shall be excluded at a party's request or on the hearing officer's own initiative.
 - 9.9.3 Documentary evidence shall be received in evidence in the form of true copies of the original.
 - 9.9.4 Documentary and other physical evidence shall be authenticated or identified by any reasonable means that shows that the matter in question is what the proponent claims it to be.
 - 9.9.5 The experience, technical competence and specialized knowledge of the hearing officer, the Department or the Department's staff shall be used in the evaluation of evidence.
 - 9.9.6 Evidence on which the hearing officer shall base his or her decision is limited to the following:
 - 9.9.6.1 all evidence, including any records, investigation reports and documents in the Department's possession of which the Department desires to avail itself as evidence in making a decision that is offered and made a part of the record of the proceeding; and
 - 9.9.6.2 testimony and exhibits introduced by the parties.
 - 9.9.7 The record shall include all briefs, proposed findings and exceptions and shall show the ruling on each finding, exception or conclusion presented.
 - 9.9.8 A party to a hearing shall submit to the hearing officer, and to all other parties to the hearing, all documents to be introduced at the hearing no later than five business days from the scheduled hearing date to insure the hearing officer and other parties receive the documents prior to the hearing.
 - 9.9.9 The Department may choose to:
 - 9.9.9.1 issue subpoenas for witnesses and other sources of evidence, either on the agency's initiative or at the request of any party; and

- 9.9.9.2 administer oaths to witnesses; limit unduly repetitive proof, rebuttal and cross-examination.
- 9.10 Conduct of proceeding: Unless the hearing officer reasonably determines a different procedure is appropriate, the hearing shall be conducted in accordance with the procedures set forth in this rule. The following procedures shall apply:
- 9.10.1 the Division shall present an opening statement on the merits and the Cardholder shall make a statement of the defense or reserve the statement until presentation of that party's case;
 - 9.10.2 after the opening statements, if made, the Division shall present its case in chief in support of the Division's petition;
 - 9.10.3 upon the conclusion of the Division's case, the Cardholder shall present its case in defense;
 - 9.10.4 upon conclusion of the Cardholder's case, the Division shall present rebuttal evidence;
 - 9.10.5 after presentation of the evidence by the parties, the Division shall present a closing argument; the Cardholder then shall present its closing argument and the Division shall present a rebuttal argument; and
 - 9.10.6 thereafter, the matter shall be submitted for recommendation by the hearing officer.
- 9.11 Continuances: The hearing officer shall not grant a continuance except for good cause shown. A motion to continue a hearing shall be made at least 10 calendar days before the hearing date.
- 9.12 Telephonic hearings:
- 9.12.1 Any party requesting a telephonic hearing shall do so within 10 business days of the date of the notice. Immediately after the parties agree to conduct the hearing by telephone, notice of the telephonic hearing shall be made to all parties and shall include all necessary telephone numbers.
 - 9.12.2 Any party that has agreed to a telephonic hearing, but subsequently requests an in-person hearing shall do so in writing to the hearing officer no later than 10 calendar days before the scheduled date of the hearing. The decision to grant or deny the request for an in-person hearing shall be at the discretion of the hearing officer for good cause shown. The hearing officer's decision to grant or deny the hearing shall be issued in writing and shall include the specific reasons for granting or denying the request. Should the hearing officer grant the request, the hearing shall be rescheduled to a time convenient for all parties. Should the hearing officer deny the request, the telephonic hearing shall proceed as scheduled.
 - 9.12.3 The location or locations of the parties during the hearing shall have a speaker telephone and facsimile machine available so that all shall hear the proceedings and documents shall be transmitted between witnesses and the hearing officer.
 - 9.12.4 The Cardholder shall initiate the telephone call. The Division is responsible for ensuring the telephone number to the Division's location for the telephonic hearing is accurate and the Division representative is available at said telephone number at the time the hearing is to commence. Failure to provide the correct telephone number or failure to be available at the commencement of the hearing shall be treated as a failure to appear and shall subject the petitioner to a default judgment.
 - 9.12.5 The in-person presence of some parties or witnesses at the hearing does not prevent the participation of other parties or witnesses by telephone with prior approval of the hearing officer.
- 9.13 Recommended action and final decision:
- 9.13.1 At the request of the hearing officer or upon motion by either party granted by the hearing officer, and before the hearing officer recommends action by the Secretary, the parties shall submit briefs including findings of fact and conclusions of law for consideration by the hearing officer. The hearing officer holds the discretion to request briefs or grant a motion to submit briefs on any point of law deemed appropriate by the hearing officer. Briefs submitted shall include supporting reasons for any findings or legal conclusions and citations to the record and to relevant law. Should the hearing officer request briefs or grant a party's motion to submit briefs, the hearing shall be continued until the hearing officer has given the briefs sufficient consideration and brings the hearing to a close. The hearing, however, shall be completed no later than 45 calendar days from the date of continuance.
 - 9.13.2 No more than 30 calendar days after completion of the hearing, the hearing officer shall prepare a written decision containing recommendation of action to be taken by the Secretary. The recommendation shall propose to sustain, modify or reverse the initial decision of the Department or the Department's agent.
 - 9.13.3 The Secretary shall accept, reject or modify the hearing officer's recommendation no later than 10 calendar days after receipt of the hearing officer's recommendation. The final decision or order shall be issued in writing and shall include:
 - 9.13.3.1 a brief summary of the evidence,
 - 9.13.3.2 a statement of findings of fact based upon the evidence,
 - 9.13.3.3 conclusions and the reasons thereof, on all material issues of fact, law or discretion involved,
 - 9.13.3.4 any other conclusions required by law of the Department, and

9.13.3.5 a concise statement of the Department's specific determination or action taken to sustain, modify or reverse the initial decision of the Department or the Department's agent.

9.13.3.6 Service shall be made by registered or certified mail.

9.13.4 The final decision or order shall be public information and shall become a part of the record.

17 DE Reg. 738 (01/01/14)

10.0 Severability

In the event any particular clause or section of these Regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full effect.

15 DE Reg. 1728 (06/01/12)

17 DE Reg. 738 (01/01/14)

11.0 Variance

11.1 A licensee may seek a variance from these Regulations by making a request for variance to the Division. The Division may grant a variance by modifying or waiving the requirements of these Regulations if in the opinion of the Division a health hazard or nuisance will not result from the variance.

11.2 A variance shall not be transferable from person to person, nor from location to location.

11.3 If a variance is granted, the Division shall retain the information specified below in its records for the variance:

11.3.1 A statement of the proposed variance of the requirement of these Regulations, citing the relevant section of these Regulations;

11.3.2 An analysis of the rationale for how the potential public health hazards or nuisances will be alternatively addressed by the proposal; and

11.3.3 Any other information requested by the Division that may be deemed necessary to render judgment.

11.4 A variance is rendered void upon occurrence of one or more of the following: the physical facility is demolished; a remodeling project in the facility includes the area(s) addressed in the variance.

19 DE Reg. 91 (08/01/15) (Emer.)